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## BECKMAN

### Summary of Safety & Effectiveness IMAGE™ Immunochemistry System C-Reactive Protein (CRP) Reagent

1.0 **Submitted By:**

Annette Hellie  
Regulatory Specialist, Product Submissions  
Beckman Instruments, Inc.  
200 S. Kraemer Blvd., W-337  
Brea, California 92822-8000  
Telephone: (714) 993-8767  
FAX: (714) 961-4457

2.0 **Date Submitted:**

06 Aug-1996

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMAGE™ Immunochemistry System C-Reactive Protein (CRP) Reagent

3.2 **Classification Names**

C-reactive protein immunological test system(21 CFR 866.5270)

4.0 **Predicate Device(s):**

Behring N Latex CRP

5.0 **Description:**

The IMAGE Immunochemistry Systems C-reactive protein (CRP) reagent, in conjunction with Beckman CAL 5 Plus, is intended for use in the quantitative determination of human C-reactive protein concentrations in human serum and plasma samples.

6.0 **Intended Use:**

The IMAGE Immunochemistry Systems C-reactive protein (CRP) reagent, in conjunction with Beckman CAL 5 Plus, is intended for use in the quantitative determination of human C-reactive protein concentrations in human serum and plasma samples by rate nephelometry. This assay is designed for use with Beckman's IMAGE Immunochemistry System.

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**7.0 Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
<b>SIMILARITIES</b>		
IMAGE System (CRP) Reagent	Intended Use	Same as Behring N Latex CRP
	Nephelometric methodology	Same as Behring N Latex CRP
	Use of Latex particle technology	Same as Behring N Latex CRP
<b>DIFFERENCES</b>		
IMAGE System (CRP) Reagent	Form of reagent	the IMAGE CRP is liquid stable while Behring N Latex CRP reagent is lyophilized
	Antibody source	IMAGE CRP uses goat while Behring N Latex CRP uses rabbit.
	Stability	IMAGE CRP is stable for 14 days once opened, properly stored while Behring N Latex CRP reagent is stable for one week following reconstitution.

## 8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Behring N Latex CRP Reagent to the IMMAGE CRP Reagent.

### Method Comparison Study Results IMMAGE CRP Reagent vs. Behring N Latex CRP Reagent

Analyte	Slope	Intercept	r	Predicate
IMMAGE CRP	1.037	-0.06	0.991	Behring N Latex CRP

### Stability Study Results

Reagent	Product Claim
IMMAGE CRP	24 month shelf-life 14 day open container stability 14 day calibration stability

### Estimated Within-Run Imprecision

MATERIAL	MEAN (mg/dL)	SD (mg/dL)	%CV	Number of Results
CRP Reagent				
Level 1	1.65	0.134	8.1	80
Level 2	5.41	0.165	3.1	80
Level 3	12.6	0.22	1.8	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.